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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/593,600

05/16/2007

Alfred Niederberger

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EXAMINER

LAWSON, MATTHEW JAMES

ART UNIT

PAPER NUMBER

3775

MAIL DATE

DELIVERY MODE

08/18/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/593,600	<b>Applicant(s)</b> NIEDERBERGER ET AL.	
	<b>Examiner</b> MATTHEW LAWSON	<b>Art Unit</b> 3775	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 16 May 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 11-30 is/are pending in the application.
- 4a) Of the above claim(s) 22-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11-21 and 30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 September 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/16/2007, 5/16/2007, 10/8/2008</u> .                         | 6) <input type="checkbox"/> Other: _____                          |



**DETAILED ACTION**

***Election/Restrictions***

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 11-21, and 30 drawn to a bone screw.

Group II, claim(s) 22-29, drawn to a method for inserting a bone screw.

2. The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Groups I and II share the same special technical feature/corresponding feature of a ball and socket joint, *i.e.* rotatably connected sections. The two groups lack unity *a posteriori* in view of Kriek (US 6,375,684).

3. During a telephone conversation with Attorney Patrick Fay on August 6<sup>th</sup>, 2009 a provisional election was made without traverse to prosecute the invention of Group I, claims 11-21, and 30. Affirmation of this election must be made by applicant in replying to this Office action. Claims 12-29 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 12 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The applicant claims “the ball has a substantially octagonal shape.” It is unclear how substantially octagonal differs from being octagonal and not being octagonal at all.

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 11-14, 16-18, 21, and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Kriek (US 6,375,684).

Regarding claims 11, 13-14, 16-18, 21, and 30, Kriek discloses a bone screw comprising a head (see figure below), a shaft (see figure below) having a longitudinal axis (see figure below), a proximal section (see figure below) adjoining the head, and a

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distal section (see figure below); wherein the distal section is attached to the proximal section by way of a ball-and-socket joint (208, figure 17), wherein the distal section comprises the ball (209, figure 17), and the proximal section comprises the socket (210, figure 17), wherein the proximal section is at least partially threaded (206, figure 17) and the distal section is at least partially threaded (203, figure 17), wherein the length of the shaft is constant (figure 17) and the proximal section has a larger diameter than the distal section (figure 17), and the distal section is allowed to deflect no more than about 90 degrees relative to the longitudinal axis (figure 17). The distal section is rotatable relative to the proximal section about the longitudinal axis (c4, l49-51). The distal section being polyaxially associated with the proximal section (column 4, lines 49-51).

According to another view Kriek discloses, a bone screw comprising a head (see figure below), a shaft (see figure below) having a longitudinal axis (see figure below), a proximal section (see figure below) adjoining the head, and a distal section (see figure below); wherein the distal section is attached to the proximal section by way of a ball-and-socket joint (208, figure 17), wherein the distal section comprises the ball (209, figure 17), and the proximal section comprises the socket (210, figure 17), wherein the proximal section is at least partially threaded (203, figure 17) and the distal section is at least partially threaded (206, figure 17).

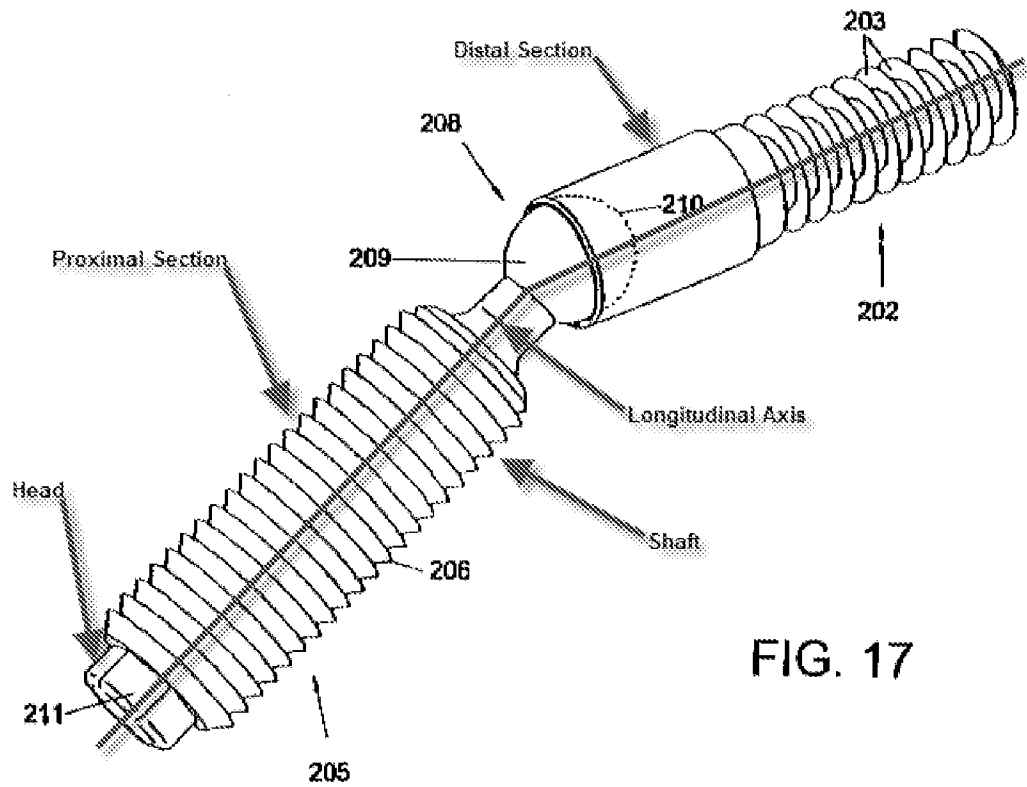


FIG. 17

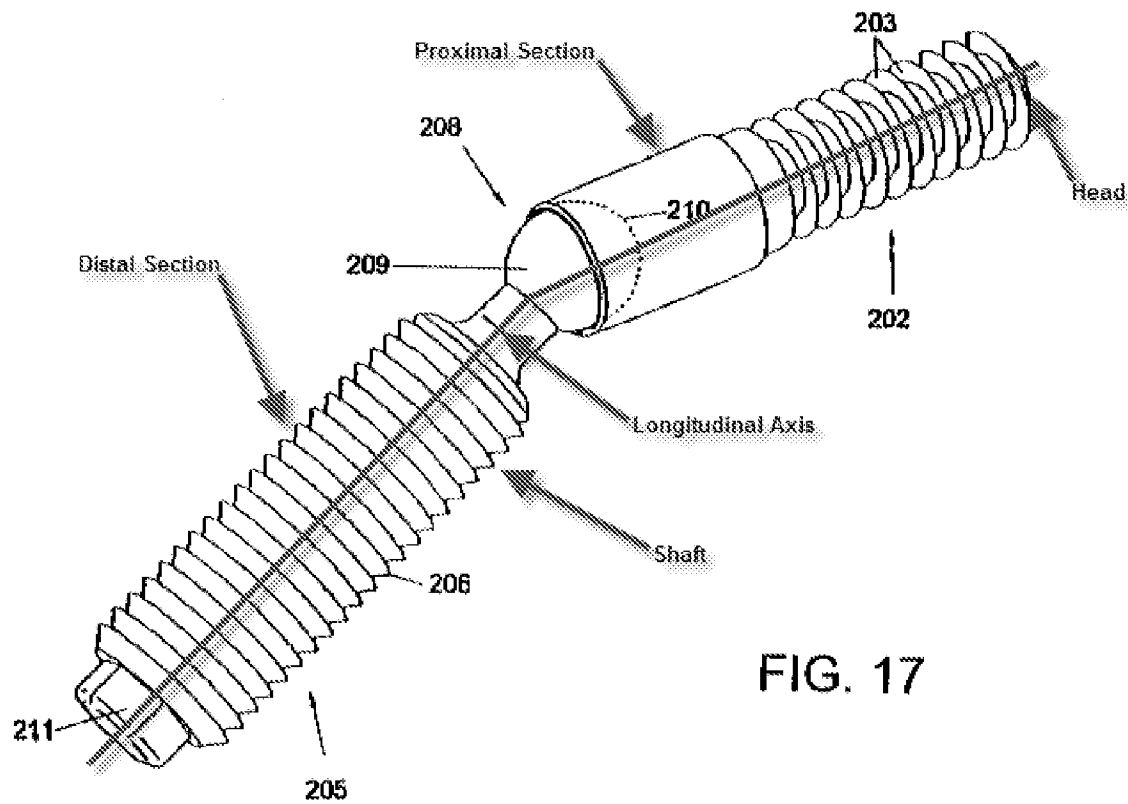
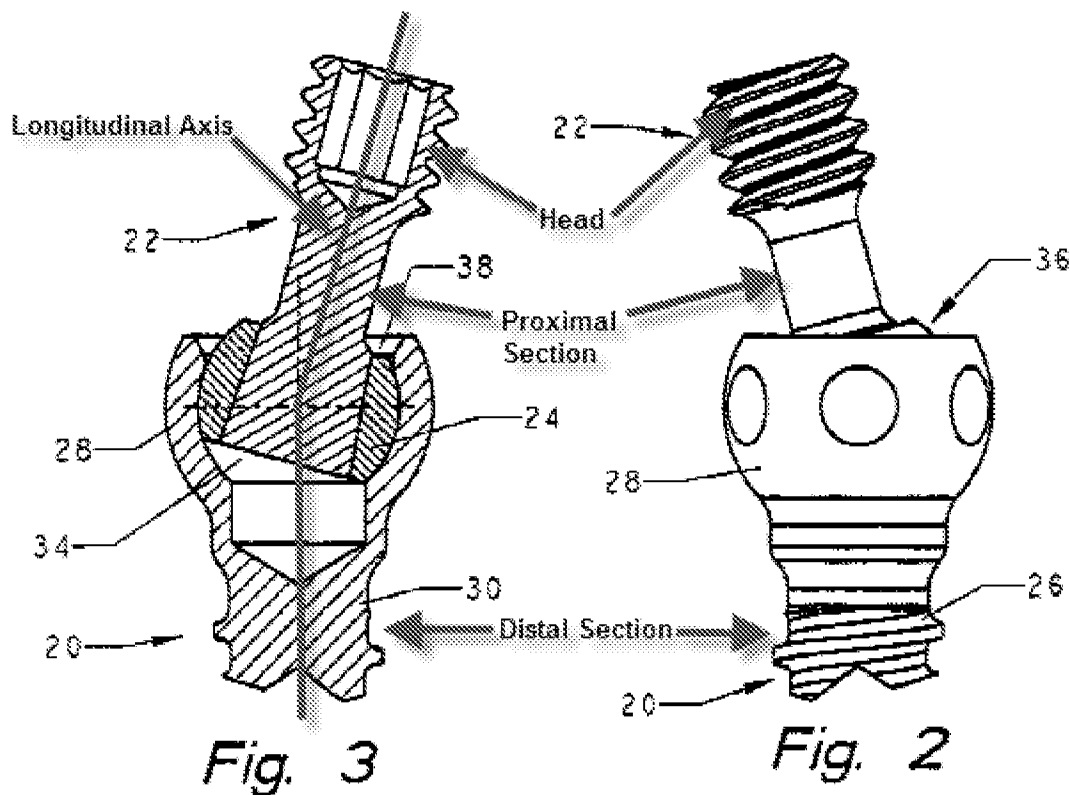


FIG. 17

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8. Claims 11, 18-19 are rejected under 35 U.S.C. 102(e) as being anticipated by Doubler et al. (US 6,887,242).

Doubler et al. disclose a bone screw comprising a head (see figure below), a shaft (see figure below) having a longitudinal axis (see figure below), a proximal section (22, figure 1) adjoining the head, and a distal section (20, figure 1); wherein the distal section is attached to the proximal section by way of a ball-and-socket joint (abstract), Wherein the distal section is allowed to deflect no more than about 30 degrees relative to the longitudinal axis (figures 2-3).



9. Claims 1 and 15 are rejected under 35 U.S.C. 102(e) as being anticipated by Landry et al. (US 2004/0143265).

Landry et al. disclose a bone screw comprising a head (106, figure 1), a shaft

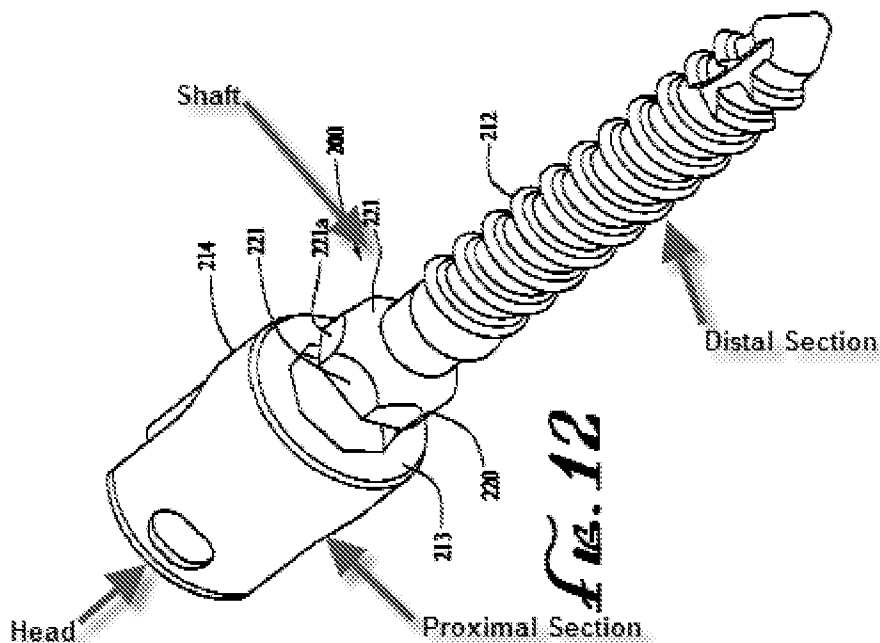


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(102, figure 1) having a longitudinal axis, a proximal section (112, figure 2) adjoining the head, and a distal section (108, figure 2); wherein the distal section is attached to the proximal section by way of a ball-and-socket joint (¶152); wherein the shaft is cannulated (¶177, figures 6, 23, 40-43).

10. Claims 11 and 20 are rejected under 35 U.S.C. 102(e) as being anticipated by Purcell et al. (US 2004/0236330).

Purcell et al. disclose a bone screw comprising a head (see figure below), a shaft (see figure below) having a longitudinal axis, a proximal section (see figure below) adjoining the head, and a distal section (see figure below); wherein the distal section is attached to the proximal section by way of a ball-and-socket joint (abstract), wherein the ball has a substantially octagonal shape (figures 12-13, ¶39).



11. **Conclusion**

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. **See attached PTO-892.**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MATTHEW LAWSON whose telephone number is (571)270-7375. The examiner can normally be reached on M-F, 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas Barrett can be reached on 571-272-4746. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. L./  
Examiner, Art Unit 3775

/Thomas C. Barrett/  
Supervisory Patent Examiner, Art  
Unit 3775